DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 24 1996

Re: Differin Solution (Re. 34,440) (Application 3)

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. Re. 34,440 filed by Centre International de Recherches Dermatologiques ("CIRD") under 35 U.S.C. § 156. The human drug product claimed by the patent is Differin Solution (Re. 34,440) (Application 3) (adapalene), which was assigned New Drug Application (NDA) No. 20-338.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product.

The NDA was approved on May 31, 1996, which makes the submission of the patent term extension application on July 26, 1996, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Norman H. Stepno
Burns, Doane, Swecker & Mathis, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 24 1996

Re: Differin Topical Gel (Re. 34,440) (Application 3)

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. Re. 34,440 filed by Centre International de Recherches Dermatologiques ("CIRD") under 35 U.S.C. § 156. The human drug product claimed by the patent is Differin Topical Gel (Re. 34,440) (Application 3) (adapalene), which was assigned New Drug Application (NDA) No. 20-380.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product.

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Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

OCT 31 1996

Philip L. Bateman
P.O. Box 1105
Decatur, IL 62525

In re Inventive Products , Inc.
Request for Patent Term Extension
U.S. Patent No. Re. 34,353

NOTICE OF
DEFICIENCIES

The application for extension of the term of U.S. Patent No. Re. 34,353, which issued August 24, 1993, was received in the Patent and Trademark Office on February 20, 1996.

The application is informal because it fails to satisfy all of the requirements of 37 CFR 1.740(a). Under § 740(a), a formal application for the extension of patent term shall include, in part:

> (10) A statement beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows: . . .
>
> (v) For a patent claiming a medical device, the effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available substantiation of that date; the date on which the application for product approval or notice of completion of a product development protocol under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application or protocol; and the date on which the application was approved or the protocol declared to be completed.
>
> (11) A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; ...
>
> (17) An oath or declaration as set forth in paragraph (b) of this section.

As to item (10), the respective dates (effective date of the IDE or the date the first clinical investigation began if no IDE was submitted; the date on which the application for product approval or notice of completion of a product development protocol was initially submitted; and the date on which the product was approved or the protocol was declared to be completed) , the IDE number, if applicable, and number of the application for product approval under section 515 of the FFDCA need to be set forth.

As to item (11), on page 5 of the patent term extension application applicant describes certain "significant activities during the regulatory review period." However, the "significant activities" required by 37 CFR 1.740(a)(11) are the activities of the applicant for patent term extension or its agent before the Food and Drug Administration which lead to the approval of the product for commercial marketing and it is these activities which must be described. Note Exhibit E-1 of the application for patent term extension for U.S. Patent No. 4,587,258, copy enclosed.

As to item (17), the required oath or declaration has not been included. 37 CFR 1.740(b) states:

> Any oath or declaration submitted in compliance with paragraph (a) of this section must be signed by the owner of record of the patent or its agent, specifically identify the papers and the patent for which an extension is sought and aver that the person signing the oath or declaration:
>
> (l) Is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters.
>
> (2) Has reviewed and understands the contents of the application being submitted pursuant to this section;
>
> (3) Believes the patent is subject to extension pursuant to § 1.710;
>
> (4) Believes an extension of the length claimed is justified under 35 U.S.C. 156 and the applicable regulations; and
>
> (5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720.

Accordingly, an oath or declaration in compliance with 37 CFR 1.740(b) is required.

The application for extension is informal because it fails to satisfy subsections (a)(10)(v), (a)(11), and (a) (17) set forth above. Applicant is given ONE MONTH from the date of this decision in which to file all the missing information noted above. Alternatively, as stated in 37 CFR 1.740 (c) applicant may seek to have this holding reviewed by filing a petition with the required fee, as

necessary, pursuant to 1.181, l.182 or l.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth herein are subject to the provisions of 37 CFR 1.136.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box DAC
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries should be directed to Karin Tyson at (703) 306-3159.

H. Bernstein

Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

Attachment- Application for patent term extension for U.S. Patent No. 4,587,256, including Exhibit E-1

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